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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/976,746 | 10/12/2001 | Michael A. McDonald | 004367.00005 | 2198 |

22908 7590 07/24/2003
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EXAMINER

HARTLEY, MICHAEL G

ART UNIT PAPER NUMBER

1616

DATE MAILED: 07/24/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,746

Applicant(s)

MCDONALD ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 8 is acknowledged.

The election of species of Gd as the metal and protein as the shell material is further acknowledged. The traversal of the elected species has been considered but is not found persuasive because the election of species was required for searching purposes, as the various shell materials set forth in claim, i.e., liposomes, albumin, antibody shell, dextrose, etc., are distinct and would be burdensome to search all of these distinct shell materials. In accordance with election of species practice, the search will be extended if the elected species is not found.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-8, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grinstaff (US 5,505,932).

Grinstaff discloses a contrast agent composition comprising one or more metal particles and one or more microsphere shells that encapsulate the metal particles, see abstract and column 8, lines 30-44. The metals used in the particles include manganese, as well as gadolinium, etc., see columns 8-9. The particles are 3 to 10 nm (30 to 100 Angstroms) in size, which is within the claimed size range. The shell of the microsphere is made of a protein, i.e., albumin, see column 12, line 35-36. The compositions are useful in various imaging modalities, see columns 4-5.

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Claims 1, 2, 4-8, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger (US 6,416,740).

Unger discloses a contrast agent composition comprising one or more metal particles and one or more microsphere shells which encapsulate the metal particles. For example, Unger discloses that various vesicles may be used in the compositions, including proteins (i.e., albumins), as the shell material, see columns 5 and 10. The vesicles are used to encapsulate the paramagnetic particles, which are 10 to 15 nm (10 to 150 Angstroms) in size, which is within the claimed size range, see column 37. The metals include manganese, as well as Gd, see columns 35-37. The compositions are useful in various imaging modalities, see column 35, lines 20+.

Claims 1, 7, 8, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Widder (US 4,849,210).

Widder discloses a contrast agent composition comprising one or more metal particles and one or more microsphere shells which encapsulate the metal particles, see column 2, lines 19+. The shell material of the microspheres is human serum albumin, see column 3, lines 56-58 and 10. The vesicles are used to encapsulate the paramagnetic particles, which are not over 300 Angstroms in size, which is within the claimed size range, see column 2, lines 24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Grinstaff (US 5,505,932); Unger (US 6,416,740) or Widder (US 4,849,210) in view of Gordon (US 4,735,796).

Grinstaff, Unger and Widder all disclose a contrast agent composition comprising one or more metal particles and one or more microsphere shells which encapsulate the metal particles, wherein various metal particles and metal oxide particles may be used, but, they fail to specifically disclose that the particles are gadolinium oxide particles. However, the use of gadolinium oxide particles as an effective contrast agent is well known in the art, as shown by Gordon.

Gordon discloses paramagnetic contrast agents comprising metal particles and teaches that gadolinium oxide is known to be useful as a contrast agent and equivalent to other metal oxide particles, see column 6.

It would have been obvious to one of ordinary skill in the art to substitute the paramagnetic metal oxide particles in the compositions disclosed any one of Grinstaff, Unger or Widder to be gadolinium oxide particles because such particles are well known to be equivalent to the metal and/or gadolinium particles disclosed by Grinstaff, Unger or Widder, as shown by Gordon. Since Grinstaff, Unger and Widder all teach the use of metal oxide particles and gadolinium oxide particles are known to be an effective contrast agent that is equivalent to other metal oxides, as shown by Gordon, one of ordinary skill in the art would have been motivated to use Gd oxide particles as the metal oxide. Also, Gd is a well known as a preferred paramagnetic metal in such contrast agents, as shown by Unger (col. 35, line 47), Grinstaff (col. 5, lines 25+) and Widder (col. 1, lines 42+).

Conclusion

No claims are allowed at this time.

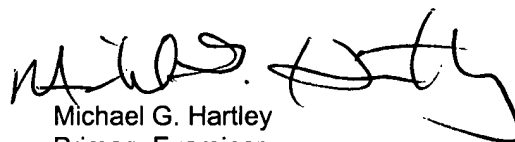
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where

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this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "Michael G. Hartley", is written over a printed name and title.

Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
July 21, 2003